ThermoFisher
SCIENTIFIC

OCT 3 ' 2007

510(k) SUMMARY

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K071580

A. Introduction:

According to the requirements of 21 CFR 807.92 the following information provides sufficent detail to understand the basis for a determination of substantial equivalence.

B. Submitter's information

Name:	Thermo Fisher Scientific Oy
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Phone:	+358 (9) 329 100 tel
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Contact person:	Päivi Sormunen, Vice President of QRC
Date of Preparation:	June 6th, 2007

C. Device name

Proprietary name:	AST / GOT (IFCC), codes 981363 and 981771
Common name:	AST / GOT (IFCC)
Classification:	Clinical Chemistry
Class:	II
Product Code:	CIT

Auxiliary product

Proprietary name:	Pyridoxal Phosphate, code 981839
Common name:	Pyridoxal Phosphate

Proprietary name:	eCal, code 981830
Common Name:	Calibrator, Multi-Analyte Mixture
Classification:	Clinical Chemistry
Class:	II
Product Code:	JIX

Proprietary name:	Nortrol, code 981043
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY

Proprietary name:	Abtrol, code 981044
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY

D. Intended Use

AST/ GOT (IFCC)
For in vitro diagnostic use in the quantitative determination of aspartate aminotransferase (L-Aspartate: 2-Oxoglutarate Aminotransferase (AST), EC 2.6.1.1) activity in human serum or plasma on T60 instrument.

Pyridoxal Phosphate
Auxiliary reagent for in vitro diagnostic use in the quantitative determination of AST (GOT) codes 981363 and 981771, activity according to the IFCC recommendations with 3-reagent method on T60 instrument.

eCal
For *in vitro* diagnostic use on T60 instrument. eCal is used as a calibrator for enzyme tests using methods defined by Thermo Fisher Scientific Oy.

Nortrol
For *in vitro* diagnostic use for quantitative testing on T60 instrument. Nortrol is a control serum to monitor precision of the analytes listed in the separate Nortrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

Abtrol
For in vitro diagnostic use for quantitative testing on T60 instrument. Abtrol is a control serum to monitor precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

E. Indications for use

The AST/ GOT (IFCC) test system is intended for quantitative *in-vitro* diagnostic determination of the activity of the enzyme aspartate amino transferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma on T60 instrument. Measurement of aspartate amino transferase levels aids in the diagnosis and treatment of certain types of liver and heart disease.

Auxiliary product: Pyridoxal Phosphate
Auxiliary reagent for in vitro diagnostic use in the quantitative determination of ALT (GPT) and AST (GOT) codes 981363 and 981771, activity according to the IFCC recommendations with 3-reagent method on T60 instrument.

For eCal Calibrator, Nortrol and Abtrol see intended use.

F. Substantial Equivalence

Bayer Corporation, model Bayer ADVIA 1650 Chemistry System.

Bayer Corporation item: Bayer ADVIA IMS Aspartate Aminotransferase (AST) assay.

G. Substantial equivalence -similarities

AST/ GOT (IFCC) is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Bayer ADVIA IMS Aspartate Aminotransferase (AST) assay (K992136).

The following table compares the AST/ GOT (IFCC) with the predicate device.

Table 1

Attribute	**New device #1**	**Predicate device #1**
Intended Use	For *in vitro* diagnostic use in the quantitative determination of aspartate aminotransferase (L-Aspartate: 2-Oxoglutarate Aminotransferase (AST), EC 2.6.1.1) activity in human serum or plasma on T60 instrument.	For *in vitro* diagnostic use in the quantitative determination of aspartate aminotransferase activity in human serum and plasma on the ADVIA Chemistry systems. Such measurements are used mainly to determine the progress and prognosis of patients with myocardial infarction and the diagnosis and monitoring of liver disease.
Indication for Use	The AST/ GOT (IFCC) test system is intended for quantitative *in-vitro* diagnostic determination of the activity of the enzyme aspartate amino transferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma on T60 instrument. Measurement of aspartate amino transferase levels aids in the diagnosis and treatment of certain types of liver and heart disease.	See intended use.
Assay Protocol	1-reagent method: Modified IFCC reference method (without PyP) 3-reagent method: IFCC reference method	1-reagent method: Modified IFCC 3-reagent method: IFCC
Traceability/Standardization	The AST/ GOT (IFCC) 1-reagent method is traceable to the molar absorbance coefficient of NADH. The AST/ GOT (IFCC) 3-reagent method is traceable to the IFCC reference method.	The ADVIA AST and AST P5P method standardization is traceable to the IFCC reference method via patient sample correlation.

Sample Type	Serum, plasma (heparin)	Serum, plasma (Li-heparin)
Reagent Storage	Reagents in unopened vials are stable at 2…8 °C until the expiration date printed on the label when protected from light.	Unopened reagents are stable until the expiration date printed on the product label when stored at 2° – 8°C.
Expected Values	Male: < 35 U/l Female: < 31 U/l	1-reagent method: < 34 U/l 3-reagent method: 13-40 U/l
Instrument	T60 and DPC T60i, DPC T60i Kusti	ADVIA® 1650 Chemistry system.
Measuring Range	1-reagent method: 4 – 350 U/l 3-reagent method: 4 - 300 U/l	0 – 1000 U/l
Precision	**1-reagent method:** **Within run** Level 38 U/l SD= 0.5 CV(%)= 1.4 Level 101 U/l SD=0.9 CV(%)= 0.9 Level 189 U/l SD= 1.0 CV(%)= 0.5 **Between run** Level 38 U/l SD= - CV(%)= - Level 101 U/l SD=0.5 CV(%)= 0.5 Level 189 U/l SD= 1.1 CV(%)= 0.6 **Total** Level 38 U/l SD= 0.9 CV(%)= 2.4 Level 101 U/l SD= 2.0 CV(%)= 2.0 Level 189 U/l SD= 3.2 CV(%)= 1.7	**1-reagent method:** **Within run** Level 42 U/l SD= 0.8 CV(%)= 2.1 Level 188 U/l SD=1.3 CV(%)= 0.7 **Total** Level 42 U/l SD= 1.3 CV(%)= 3.3 Level 188 U/l SD= 4.1 CV(%)= 2.3 **3-reagent method:** **Within run** Level 50 U/l SD= 0.6 CV(%)= 1.5 Level 195 U/l SD=1.3 CV(%)= 1.1 **Total** Level 50 U/l SD= 1.0 CV(%)= 2.7 Level 195 U/l SD= 2.5 CV(%)= 2.0

	3-reagent method: **Within run** Level 37 U/l SD= 0.6 CV(%)= 1.5 Level 124 U/l SD=1.3 CV(%)= 1.1 Level 191 U/l SD= 1.0 CV(%)= 0.5 **Between run** Level 37 U/l SD= 0.4 CV(%)= 1.0 Level 124 U/l SD=1.4 CV(%)= 1.1 Level 191 U/l SD= 1.2 CV(%)= 0.6 **Total** Level 37 U/l SD= 1.0 CV(%)= 2.7 Level 124 U/l SD= 2.5 CV(%)= 2.0 Level 191 U/l SD= 2.9 CV(%)= 1.5	
Method Comparison	**1-reagent method:** y = 0.95x – 2.0 R = 0.992 Range 12 to 307 U/L N = 83 **3-reagent method:** y = 0.94x + 1.3 R = 0.994 Range 15 to 408 U/L N = 84	Comparison with Technicon DAX: y = 0.99x - 6.3 U/l r = 0.999 n = 111 range: 9.8 to 607.2 U/l

Limitations	**1-reagent method:** **Lipemia**: No interference found up to 150 mg/dL (1.5 g/l) of Intralipid. **Hemolysate:** Avoid hemolyzed samples. **Bilirubin, conjugated:** No interference found up to 35 mg/dL (600 µmol/l) of conjugated bilirubin. **Bilirubin, unconjugated:** No interference found up to 35 mg/dL (600 µmol/l) of unconjugated bilirubin. **3-reagent method:** **Lipemia**: No interference found up to 150 mg/dL (1.5 g/l) of Intralipid. **Hemolysate:** Avoid hemolyzed samples. **Bilirubin, conjugated:** No interference found up to 58 mg/dL (1000 µmol/l) of conjugated bilirubin. **Bilirubin, unconjugated:** No interference found up to 58 mg/dL (1000 µmol/l) of unconjugated bilirubin.	**1-reagent method:** **Lipemia (from Intralipid)**: No significant interference found up to 488 mg/dl of Intralipid. **Hemolysate:** Avoid hemolyzed samples **Bilirubin (conjugated and unconjugated):** No significant interference found up to 30 mg/dl (513 µmol/l) **3-reagent method:** (AST Sample Concentration 65 U/l) **Lipemia (from Intralipid)**: No significant interference found up to 488 mg/dl. **Hemolysate:** Avoid hemolyzed samples **Bilirubin (conjugated and unconjugated):** No significant interference found up to 30 mg/dl (513 µmol/l)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Thermo Fisher Scientific Oy
c/o Mr. Päivi Sormunen
Vice President of Reagent Business
Development and QRC
Clinical Diagnostics Finland
Ratastie 2, P.O. Box 100
FIN-01621 Vantaa, Finland

OCT 3 ˇ 2007

Re: k071580
Trade Name: AST/GOT (IFCC), Auxiliary Product: Pyridoxal Phosphate
eCal, Nortrol, Abtrol
Regulation Number: 21 CFR 862.1100
Regulation Name: Aspartate amino transferase (AST/SGOT) test system.
Regulatory Class: Class II
Product Code: CIT, JIX, JJY
Dated: August 30, 2007
Received: September 14, 2007

Dear Mr. Sormunen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K071580

Device Name: AST / GOT (IFCC)
Auxiliary product: Pyridoxal Phosphate
eCal
Nortrol
Abtrol

Indication For Use:

AST / GOT (IFCC)
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Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071580